19. The assay device of claim 18, wherein the immunoglobulin is rabbit immunoglubulin G, and the anti-human chorionic gonadotropin antibody is a murine monoclonal antibody.

20. The assay device of claim 19, wherein the direct particulate label is a colored latex particle.

REMARKS

This is in response to the Official Action mailed January 4, 2002 for the above-captioned application. Applicants request a three-month extension of time, and enclose the appropriate fee. The Examiner is authorized to charge any additional fees or credit any overpayments to Deposit Account No. 15-0610.

Claims 2-20 are pending in this application. Claims 12-20 have been added to present the assay of the invention in a different format. No new matter has been added.

In considering the claims of the invention, Applicants would like to focus the Examiner's attention on the mobile reagent. This reagent has three parts: a direct particulate label, a specific binding reagent with specificity for the analyte, and a protein which interacts in a specific binding relationship with the control line of the assay. This means that the direct particulate label is capable of binding to two different targets, one of which is the analyte and the other of which is the control line. The specification and the claims refer to a particulate label of this type as one which is co-sensitized.

The Examiner rejected claims 2-11 under 35 USC § 103 as unpatentable over the combination of Sawai et al. and May et al., further in view of Harlow and Lane. Applicants respectfully traverse this rejection.

In stating the rejection, the Examiner asserts that May et al "disclose an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be detected." The Examiner does not state where in the May et al. patent this alleged teaching is found, and Applicants respectfully submit that there is no such disclosure. In May, the mobile or "labeled reagent" is described in several embodiments. Col. 2, lines 44-51 describes a labeled reagent including a specific binding partner

for the analyte. There is no teaching of a second binding entity within the mobile, labeled reagent. Col. 2, lines 52 et seq. describe another embodiment is which the labeled reagent includes the analyte or an analyte analog. Again, there is no teaching of a second binding entity within the mobile, labeled reagent.

The lack of such a teaching can be further seen from the discussion of the control zone found in May et al. at Col. 5 line 5 et seq. In the assay of the present invention, a detectable signal in the control zone results from the interaction of the control zone and the protein part of the co-sensitized label. In May, however, the signal in the control zone results from a non-specific interaction with the specific antibody in the singly-sensitized label, from the mere passage of moisture through the control zone, or from capture of excess label by immobilization of analyte. In none of this is there a disclosure or a suggestion of a particulate label which is co-sensitized with two binding species. Thus, the basic premise of the rejection, i.e., that May et al. teaches the co-sensitized mobile reagent of the invention, is incorrect.

Applicants further note that the Examiner has asserted that Harlow and Lane teach "sensitizing a protein of interest with a non-specific protein in order to block non-specific binding." and equates this with a teaching of a con-sensitized label. The Examiner has not indicated where in Harlow and Lane this teaching is found. The closest thing Applicants have found is the disclosure on the last page of adding BSA or some other similar protein to swamp out non-specific effects. This, however, is not including BSA (or a BSA-binder) as part of a reagent, nor does it depend on a specific binding reaction between a part of a co-sensitized label and a reagent in the control zone. It is merely using an extra and unrelated protein to saturate non-specific binding sites which may be present on the substrate so that the label is not captured in the wrong location. Thus, Harlow and Lane do not teach or suggest a mobile reagent of the type claimed in the present application.

For the foregoing reasons, Applicants submit that all claims are in form for allowance. Withdrawal of the rejection and prompt allowance of the application is respectfully urged.

Respectfully Submitted,

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